IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALMIRALL, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS LLC,
Defendant.

CIVIL ACTION
NO. 19-658

PAPPERT, J. **January 25, 2021**

MEMORANDUM

Almirall sued Amneal in 2019, asserting U.S. Patent No. 9,517,219 in an attempt to stop Amneal from obtaining approval for a generic version of Almirall's ACZONE Gel 7.5%. At this stage of the litigation, the parties disagree on how to construe certain claim terms. Almirall argues no construction is necessary for the disputed terms; Amneal argues the terms and the entire patent are invalid for indefiniteness. Amneal has not met its burden of showing indefiniteness by clear and convincing evidence. And since, in the alternative, Amneal does not contest Almirall's position that no construction is necessary for the disputed terms, the Court declines to construe the disputed claim terms.

I

Almirall owns U.S. Patent No. 9,517,219, which covers ACZONE (dapsone) Gel, 7.5%, an FDA-approved topical acne treatment. Aczone 7.5% contains several ingredients, including dapsone, a polymeric viscosity builder ("PVB") comprising acrylamide/sodium acryloyldimethyl ("A/SA") and water at a level "Q.S." or as much as

is needed to complete the composition. Almirall asserted the '219 patent against Amneal after Amneal filed an Abbreviated New Drug Application for FDA approval of a generic version of Aczone 7.5%. The parties submitted a joint claim construction chart and joint brief explaining and supporting their positions on claim construction. The Court then held a claim construction hearing where the parties presented evidence mostly in the form of expert witnesses.

The parties agree on how to construe the claim terms "dapsone" and "polymeric viscosity builder." (Redacted Joint Cl. Constr. Chart 3, ECF No. 53.) Dapsone means "4,4'-diaminodiphenyl sulfone" and a PVB is "a polymer or polymer-based thickening agent." (*Id.*) The parties disagree as to how to construe the following claim terms:

- "about 2% w/w[1] to about 6% w/w of a polymeric viscosity builder comprising[2] acrylamide/sodium acryloyldimethyl taurate copolymer" (Claims 1–5);
- "wherein the polymeric viscosity builder is present at a concentration of about 4% w/w" (Claim 3); and
- "about 4% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer" (Claims 6–8).

[1] "W/w" is a technical abbreviation for "weight for weight" or "weight by weight." It represents the concentration of an ingredient in the overall composition.

[2] In patent claims, "comprising" signifies that the composition includes the stated ingredient but may also include others. So the '219 patent covers compositions that contain a PVB with A/SA and, potentially, other ingredients. By contrast, the phrase "consisting of," means that the composition includes the stated ingredients and no others.

(*Id.* at 3–13.) Almirall argues these terms need no construction. Amneal does not argue for any particular construction; instead, it argues each term is invalid as indefinite under 35 U.S.C. § 112. (*Id.*)

II

A

"[A] patent claim is that 'portion of the patent document that defines the scope of the patentee's rights.'" *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015) (quoting *Markman v. Westview Instruments, Inc.,* 517 U.S. 370, 372 (1996)). The construction of a patent is a question of law. *Markman*, 517 U.S. at 372. The purpose of claim construction "is to determin[e] the meaning and scope of the patent claims asserted to be infringed," such that the jury may then resolve the underlying infringement question. *CANVS Corp. v. United States*, 126 Fed. Cl. 106, 112 (2016) (quoting *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008)).

"[T]he words of a claim are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). The ordinary and customary meaning of a claim term "is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321; *White v. Dunbar,* 119 U.S. 47, 52 (1886) (Because the patentee is required to "define precisely what his invention is," it is "unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms."). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art

may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

In construing a claim term, the court looks first to evidence in the intrinsic record, which includes the language of the claims of patent, the patent's specification and the patent's prosecution history (*i.e.*, the record before the Patent Office). *Id.* at 1314–17; *Housey Pharm., Inc. v. Astrazeneca UK Ltd.*, 366 F.3d 1348, 1351–52 (Fed. Cir. 2004) ("Claim construction begins with the language of the claims."); *see Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*) ("Claims must be read in view of the specification, of which they are a part."), *aff'd,* 517 U.S. 370 (1996). If, after considering the intrinsic evidence, the claim remains ambiguous, the court may look to extrinsic evidence. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence."). Extrinsic evidence may not, however, be used to contradict or override intrinsic evidence. *Id.* at 1584 ("[E]xtrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language[, n]or may it contradict the import of other parts of the specification.").

B

The "definiteness" requirement derives from 35 U.S.C. § 112, ¶ 2, which requires that the claims of a patent "particularly point[ ] out and distinctly claim the subject matter which the applicant regards as his invention." This requirement is meant to

ensure that "[a] patent holder [ ] know[s] what he owns, and the public [ ] know[s] what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). "The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.*, competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.,* 309 F.3d 774, 779–80 (Fed. Cir. 2002) (citing *Warner–Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 28–29 (1997)). Thus, a patent claim must be "sufficiently precise to permit a potential competitor to determine whether or not he is infringing." *Morton Int'l, Inc. v. Cardinal Chem. Co.,* 5 F.3d 1464, 1470 (Fed. Cir. 1993).

Patent "[v]alidity and infringement are distinct issues, bearing different burdens, different presumptions, and different evidence." *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1929 (2015) (citation and quotation marks omitted). Patents have a statutory presumption of validity, so a defendant in an infringement case raising the defense of invalidity must show invalidity by clear and convincing evidence. 35 U.S.C. § 282(a); *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 97 (2011); *Cox Commc'ns, Inc. v. Sprint Commc'n Co. LP*, 838 F.3d 1224, 1228 (Fed. Cir. 2016) ("Any

fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence.").

III

A

Amneal argues principally that Claims One, Three and Six—and therefore the entire '219 patent—are invalid as indefinite. It contends that a person of ordinary skill in the art ("POSA")[3] would not be able to determine whether the PVB comprising A/SA satisfies the concentration requirements described in the claims because ingredients in the PVB overlap with ingredients in the overall composition. In particular, a PVB may contain water, which is also an independent ingredient in the overall composition. Accordingly, a POSA analyzing a final composition would not know whether to attribute individual water molecules found in the overall composition to the PVB, and thus would not be able to calculate the PVB's concentration in the final composition. (Redacted Joint Cl. Constr. Br. 2, ECF No. 110.) Amneal argues that this uncertainty renders the patent invalid for indefiniteness.

[3] The parties agree on a definition for a POSA:

> [T]he level of skill in the art is high and is at least that of a medical doctor with several years of experience in the art and the skilled physician would likely have consulted a skilled drug formulator who would possess (i) a bachelor- or master-level degree in chemistry, polymer science, pharmaceutics, or a related discipline, plus at least three years of experience in drug delivery, pharmaceutical formulations, or a related field; or (ii) a doctoral degree in chemistry, polymer science, pharmaceutics, or a related discipline, plus some experience in drug delivery, pharmaceutical formulations, or a related field.

(Redacted Joint Cl. Constr. Br. 7–8, ECF No. 110) (citation omitted).

Almirall counters that the claims are definite because a POSA would understand the scope of the disputed claim terms. In addition, it argues a POSA would be able to identify the PVB and calculate how much of that PVB she has in a composition. It posits that although whether water is "part of the thickening agent *in a particular composition* may be open to reasonable dispute, [ ] that does not render the disputed *claim term* indefinite." (Joint Cl. Constr. Br. at 17.) In other words, Almirall argues that Amneal takes a flawed approach to the issue. It says:

> Amneal's argument appears to be that if *reverse-engineering* a targeted dapsone topical formulation, a POSA would not be able to tell whether a particular water molecule is serving within the thickening agent segment, as distinguished from residing among the water molecules within the "Q.S." segment of the composition. But even if true, an inability to precisely reverse engineer an unknown formulation—so as to allocate like structures (*i.e.*, water molecules), on the one hand, to varied functions, on the other hand—does not render any of the claims indefinite.

(*Id.* at 39.)

Each side presented an expert witness at the *Markman* hearing. Amneal's expert, Dr. Mansoor Khan, testified that it is "almost impossible" for a POSA to know with reasonable certainty whether a completed composition "falls within or outside the scope" of the disputed claims. (*Markman* Hr'g Tr. 33:8–11.) In reaching that conclusion, Dr. Khan analyzed hypothetical formulations and their listed ingredients. *See, e.g.*, (*id.* at 38:1–40:17). He contended that a POSA analyzing a final composition would not be able to calculate the concentration of the PVB because the POSA would now know whether to attribute water found in the composition to the PVB or the Q.S. amount. (*Id.* at 41:5–11.) He further alleged that attributing water to the PVB or the Q.S. amount would not change the nature of the composition. (*Id.* at 43:4–25.) So, according to Dr. Khan, the exact same final composition could infringe or not infringe

based entirely on how a POSA arbitrarily chooses to attribute water molecules when evaluating a final composition. On cross-examination, Dr. Khan confirmed that a formulator submitting a product to the FDA for approval must list everything in the product and its function. (*Id.* at 81:23–82:3.) Along those lines, he explained that, in submitting its competitor product to the FDA, Amneal would have been required to identify its PVB. (*Id.* at 82:16–25.) On cross-examination, Dr. Khan was unable to answer a number of counsel's questions because he had not come prepared to address them. *See, e.g.*, (*id.* at 75:16–21).

In stark contrast to Dr. Khan, Almirall's expert witness, Dr. David Osborne, testified that a POSA "would know exactly what [the disputed claim terms] mean and would know whether their formulation was within or outside" the patent. (*Id.* at 98:1–5.) Specifically, he said that an inventor would understand "that water included in the [PVB] would be bundled together" with the other components of the PVB and that water used in the PVB would be separate from Q.S. water. (*Id.* at 107:8–19.) He also testified that the amount of water attributed to Q.S. in a formulation like Aczone 7.5% is "not boundless, and it's not arbitrary in any way, shape or form." (*Id.* at 109:9–12.) On cross-examination, Amneal emphasized Dr. Osborne's unfamiliarity with the term "polymeric viscosity builder" prior to this case. (*Id.* at 133:23–134:16.) Focusing on Dr. Osborne's initial confusion regarding the meaning of PVB, Amneal posited that "PVB doesn't have a meaning in the art," and therefore a POSA would not understand the scope of the disputed claim terms. (*Id.* at 135:4–8.) During cross-examination, Amneal summarized its position to the Court: "[A] POSA can't look at a formula with any degree of reasonable certainty and say, I'm going to allocate these ingredients to this

made-up PVB. And I'm going to do so with such confidence that I can say you've got 4 percent of this PVB. . . . [T]hat is why this patent is fundamentally indefinite." (*Id.* at 142:12–17.)

B

For the following reasons, Amneal has fallen short of showing by clear and convincing evidence that the claim terms fail to inform, with reasonable certainty, a POSA about the scope of the invention.

First, Amneal's position that the claims are indefinite because a POSA could not determine whether a completed composition infringes the '219 patent is unpersuasive. Section 112 requires that a specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). Amneal fails to establish, by clear and convincing evidence, that the disputed claim terms fail to satisfy this "clarity and precision demand." *Nautilus*, 572 U.S. at 901.

Amneal primarily argues a POSA could not reverse-engineer a completed composition to determine whether it infringes, but whether a POSA can analyze a finished product and know whether it infringes is not the aim of the definiteness requirement. The text of § 112 and relevant precedents analyzing definiteness suggest that the relevant inquiry is whether, when read, a claim term informs a POSA of the bounds of the invention so she can compete with the peace of mind that her product does not infringe the patented invention. *See Amgen Inc. v. Hoechst Marion Roussel*, Inc., 314 F.3d 1313, 1342 (Fed. Cir. 2003) (claims must be "sufficiently precise to permit a potential

competitor to determine whether or not he is infringing"); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1373 (Fed. Cir. 2008) ("The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention."). The disputed claim terms in this case do just that. A POSA reading the disputed claims would understand, with more than reasonable certainty, what it means for a PVB comprising A/SA to be present in the composition at a certain concentration. And a POSA who intends to develop a competitor product would have no problem understanding how to create that product in a way that does not infringe the '219 patent because the POSA would know whether water she adds to her composition is part of the PVB or Q.S. *See* (Hr'g Tr. at 108:16–109:12, 116:22–117:17). The fact that another POSA may come along and not know whether a randomly-selected water molecule in that composition is attributable to the PVB or Q.S. is immaterial to deciding whether the claims are definite. The definiteness requirement does not seek to ensure that a POSA can deconstruct an unknown finished composition to determine whether it infringes; it is aimed at notifying interested POSAs of the bounds of the invention so they can compete with reasonable certainty that they are not infringing a patent.

Second, the caselaw Amneal cites in support of its position is unavailing or inapplicable. For example, Amneal relies on *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1384 (Fed. Cir. 2003), in which the Federal Circuit considered an indefiniteness challenge to a claim requiring a "pharmaceutical composition . . . which comprises a synergistically effective amount of clavulanic acid." *Id.* at 1375–76. The

claim was indefinite because it could infringe or not infringe based on circumstances outside the patent and unknowable with any certainty by a POSA. More specifically, whether a composition was "synergistically effective" depended on the bacteria to which a POSA applied the composition. *Id.* at 1384. The Court concluded that the claim was indefinite because the same composition could be effective against some bacteria but not others. *Id.* Amneal argues *Geneva Pharms* applies here because a composition may infringe the '219 patent or not based on how a POSA attributes water molecules within a final composition. But that contention ignores a significant difference between the '219 patent and the patent at issue in *Geneva Pharms*—infringement of the '219 patent does not depend on unspecified outside factors, like how and to what it is applied.

Amneal also relies on *Forest Labs., Inc. v. Teva Pharms. USA, Inc.*, No. 14-121, 2016 WL 54910, at *9 (D. Del. Jan. 5, 2016), in which the Court held a patent indefinite because the disputed claim required comparison of the covered composition to an unknown benchmark. *Id.* The '219 patent claims do not call for a comparison of the composition to any unknown reference point. Instead, a POSA must calculate whether the PVB is present in the composition at a particular concentration, a task any POSA would seemingly have no problem completing. Unlike in *Forest Labs*, a POSA developing a competitor product to the '219 patent would know, based on the terms of the disputed claims, the scope of the patent and whether or not she is infringing. In other words, the '219 patent does not create "[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Nautilus*, 572 U.S. at 909–10.

Third, Amneal's evidence (mostly in the form of Dr. Khan's expert testimony) does not satisfy the clear and convincing evidentiary standard for indefiniteness. Although Amneal successfully demonstrates that, in some scenarios, a POSA who does not know how a formulator created a composition would not be able to determine whether that composition infringes the '219 patent, it does not demonstrate how a POSA reading the disputed claims would fail to understand the scope of the claim. And Amneal does not present clear and convincing evidence to overcome Almirall's position that "every pharmaceutical developer" lists the "function of ingredients alongside their identities and amounts . . . when submitting a formulation to the FDA." (Joint Cl. Constr. Br. at 44); *see* (Hr'g Tr. at 81:19–82:3) (Dr. Khan testified that a formulator must submit a list of ingredients and their functions to the FDA). Armed with that information, a POSA could easily determine whether a final composition infringes the '219 patent.

Amneal says Almirall's expert, Dr. Osborne, reveals the indefiniteness of the claims when he says water can be attributed to the PVB based on whether or not the POSA *would consider* water as part of the PVB. (Joint Cl. Constr. Br. at 62) (citation omitted). Amneal argues that "[t]his further confirms that the '[PVB] comprising [A/SA]' does not have the requisite objective boundaries rendering the claims indefinite." (*Id.*) (citing *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005)). But Dr. Osborne clarified this position at the *Markman* hearing, testifying that a POSA would not arbitrarily attribute water to the PVB or Q.S. Instead, he explained that formulators deliberately include water in the PVB or Q.S. at different stages of formulation and that those decisions impact the composition's

characteristics. (Hr'g Tr. at 108:16–109:12) (explaining that the amount of water added to a composition as Q.S. is "not boundless, and it's not arbitrary in any way, shape or form"); (*id.* at 116:22–117:17) (explaining that arbitrarily adding water to a PVB would render it useless and that a POSA would usually add the PVB once the rest of the composition is complete). Moreover, the case Amneal cites to support this position—*Datamize v. Plumtree Software*—is unpersuasive. That case involved the claim term "aesthetically pleasing," which is inherently and always subjective because it is a matter of taste, unique to each individual person. 417 F.3d at 1350. Including water in a PVB or Q.S. is fundamentally different because that choice is a matter of objective science, not a decision left to the subjective tastes of a POSA. *See* (Hr'g Tr. at 108:16–109:12, 116:22–117:17).

The indefiniteness issue boils down to a simple question: Do the claim terms inform, with reasonable certainty, those skilled in the art about the scope of the invention? In this case, the answer is yes. Having considered the relevant legal standards and the parties' evidence, the Court concludes that Amneal fails to overcome the '219 patent's presumption of validity and meet its burden to show indefiniteness by clear and convincing evidence.

B

Having rejected Amneal's definiteness arguments, the Court declines to construe the disputed claim terms. Almirall argues no construction is necessary and Amneal advances no argument as to how the Court should construe the claims. Thus, there is no dispute between the parties as to the meaning of these terms. Plus, the terms are

not complex. A POSA would easily understand what it means for a thickening agent comprising A/SA to be present in a composition at a certain concentration.

An appropriate Order follows.

BY THE COURT:

/s/ Gerald J. Pappert
GERALD J. PAPPERT, J.